Uplizna™ (inebilizumab-cdon) Intravenous injection

Effective Date: January 1, 2021
Number: MG.MM.PH.317

Medical Guideline Disclaimer
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Definitions

Uplizna (inebilizumab-cdon) is a CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive

Length of Authorization

Initial authorization will be for no more than 6 months and reauthorization will be for no more than 12 months.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:
- 300 billable units on day 1 and 15, then 300 billable units every 6 months (beginning 6 months after the first dose)

Guideline

I. INITIAL APPROVAL CRITERIA
Coverage is provided in the following condition:
Neuromyelitis Optica Spectrum Disorder (NMOSD)

- Patient is 18 years of age and older; **AND**
- Prescribed by a neurologist; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**
- Patient has been evaluated and screened for the presence hepatitis B virus (HBV) prior to initiating treatment; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Submission of medical records (e.g. chart notes, laboratory values, etc.) to support the diagnosis of neuromyelitis optica spectrum disorder (NMOSD) by a neurologist confirming all of the following:
  - Past medical history of one of the following:
    - Optic neuritis
    - Acute myelitis
    - Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting
    - Acute brainstem syndrome
    - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
    - Symptomatic cerebral syndrome with NMOSD-typical brain lesions;  **AND**
  - Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMP-IgG antibodies; **AND**
  - Diagnosis of multiple sclerosis or other diagnoses have been ruled out; **AND**
- Patient has not failed a previous course of Uplizna therapy; **AND**
- History of failure of, contraindication, or intolerance to rituximab therapy; **AND**
- One of the following:
  - History of at least one relapse during the previous 12 months prior to initiating Uplizna
  - History of at least two relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Uplizna; **AND**
- Patient is not receiving Uplizna in combination with any of the following:
  - Disease modifying therapies for the treatment of multiple sclerosis (e.g. Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.)
  - Immunosuppressive therapy (IST), such as oral or intravenous corticosteroids, with the exception of premedication for treatment
  - Soliris

II. RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified above; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: tuberculosis (TB) infections, hepatitis B reactivation, infusion reactions, serious infections, Progressive Multifocal Leukoencephalopathy (PML), hypogammaglobulinemia, etc.; **AND**
• Patient is receiving ongoing monitoring for presence of TB or other active infections; **AND**
• Disease response indicated by one or more of the following:
  o Reduction in the number and/or severity of relapses or signs and symptoms of NMOSD
• Patient is not receiving Uplizna in combination with any of the following:
  o Disease modifying therapies for the treatment of multiple sclerosis (e.g. Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.)
  o Immunosuppressive therapy (IST), such as oral or intravenous corticosteroids, with the exception of premedication for treatment
  o Soliris

**Limitations/Exclusions**

1. Uplizna (inebilizumab-cdon) is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

**Applicable Procedure Codes**

| J1823 | Injection, inebilizumab-cdon; 1 billable unit = 1 mg |

**Applicable NDCs**

| 72677-0551-01 | Uplizna, one carton containing three 100 mg/10 mL single-dose vials |

**Applicable Diagnosis Codes**

| G36.0 | Neuromyelitis optica (Devic) |

**Revision History:**

| 1/1/2021 | Updated J-Code: J1823 |

**References**